



TRANSMITTED BY FACSIMILE

Ms. Bobbi Woodward
Manager, Regulatory Affairs
Galderma Laboratories, L.P.
14501 N. Freeway
Fort Worth, TX 76177

/s/

Rebecca Williams
10/1/01 04:07:50 PM

RE: NDA# 20-380
Differin (adapalene gel) Gel, 0.1%
MACMIS ID#: 10377

Dear Ms. Woodward:

This letter objects to Galderma Laboratories', L.P. (Galderma) dissemination of violative promotional materials for Differin (adapalene gel) Gel, 0.1%. As part of its monitoring program, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has become aware of two direct-to-consumer (DTC) television (TV) broadcast advertisements for Differin that are in violation of the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations. The DTC broadcast ads ("My Sister's Wedding," 60 and 90 seconds, DIF220A), submitted on Form FDA 2253, are violative for the reason described below.

The broadcast ads lack fair balance because the communication of important risk information associated with the use of Differin is inadequate. During the audio presentation of the major risk information, there are numerous visual distractions that interfere with the viewer's ability to listen to and process the audio information disclosing the most important risks associated with use of Differin. This includes numerous scene changes and quick camera movements. Therefore, the risk information is not presented with a prominence reasonably comparable to the presentation of the effectiveness of the drug.

Galderma should immediately discontinue these and all other promotional materials and activities for Differin that contain the same or similar presentations. We request that Galderma respond in writing with its intent to discontinue such use. We should receive your written response no later than October 16, 2001. This response should list similarly violative materials with a description of the method for discontinuation and the discontinuation date.

Ms. Bobbi Woodward
Galderma Laboratories, L.P.
NDA 20-380

Page 2

Your response should be directed to Rebecca Williams, PharmD by facsimile at (301) 594-6771, or at the Food and Drug Administration, Division of Drug Marketing, Advertising, and Communications, HFD-42, Rm 17-B-20, 5600 Fishers Lane, Rockville, MD 20857. DDMAC reminds Galderma that only written communications are considered official.

In all future correspondence regarding this particular matter, please refer to MACMIS ID# 10377 in addition to the NDA number.

Sincerely,

{See appended electronic signature page}

Rebecca Williams, PharmD
Regulatory Review Officer
Division of Drug Marketing,
Advertising, and Communications

TELEVISION SCRIPTJOB # GAD 568

CLIENT Galderma
 PRODUCT Differin Gel
 TITLE "My Sister's Wedding"
 CODE DIF-11-60
 LENGTH :60
 DATE

AS PRODUCED 9/13/01 @ []
BY []

Page 1

VIDEO**AUDIO**

- | | |
|--|--|
| <p>1. (Entire spot shot documentary feel, cut back and forth between Meg and Sue talking to camera and real life scenes which they narrate)
 Meg and Sue are both mid-twenties, attractive women)</p> <p>Open on wedding invitations, coffee cup, pen/paper. Camera pans to show back of sister's head, mother's head. Camera shows face of Meg. They're planning a wedding. Meg has problem skin.</p> | <p>(SFX: ambient sound, music, sound design as appropriate)</p> <p><u>MEG VO</u>: My problem? It's not my older sister's wedding ...</p> |
| <p>2. Cut to swish pan of table.</p> | <p><u>MEG VO</u>: My problem is my skin. My acne.</p> |
| <p>3. Cut to Meg in her bathroom.</p> | <p><u>MEG VO</u>: I don't want this for the wedding.</p> |
| <p>4. Cut to Meg, limbo.
 Script: 3 months before the wedding</p> | <p><u>MEG OC</u>: So today, I'm starting something my cousin told me about.</p> |
| <p>5. Cut to Sue with Differin tube.
 Half used.</p> | <p><u>SUE OC</u>: I told Meg about Differin Gel.</p> |
| <p>6. Cut to Differin application.
 SUPER: Available by prescription only.</p> | <p><u>SUE VO</u>: I had worse skin than her.</p> |
| <p>7. Cut to Sue in limbo.</p> | <p><u>SUE OC</u>: And look at me now.</p> |

TELEVISION SCRIPT

JOB # GAD 568

CLIENT	Galderma
PRODUCT	Differin Gel
TITLE	"My Sister's Wedding"
CODE	DIF-11-60
LENGTH	:60
DATE	AS PRODUCED 9/13/01 @ []

BY []

VIDEO

AUDIO

8. Cut to tabletop of Differin and new brochure.

SUPER:

See our ad in ____ magazine.
(hold for 2 seconds)

9. Cut to Meg, at home, in bathroom at night. Applying Differin Gel.

10. Letterbox, real before/after and product tube.

SUPER: Before/After

1-800-000-0000

and product

SUPER:

Individual results may vary.
(show product tube)

11. Another real before/after.

SUPER:

Individual results may vary.

12. Cut to Meg on camera.

13. Letterbox montage of . Also intercut with Sue and Meg, separately putting on Differin Gel at night, in front of their bathroom mirrors.

SUPER:

1-800-000-0000

SUPER: www.DifferinGel.com

SUPER:

Now available as a cream

SUPER: Use of sunscreen is recommended.

.....
SUE VO (narrating): My doctor said Differin Gel may change

how your skin cells work.

You use a little dab at night. It's oil-free with no alcohol.

All I can say is ... having clearer skin,

it changes everything.

MEG OC (narrating): I see improvement.

(MUSIC under)

ANNC VO:

Itching, dryness, redness, burning or peeling may occur especially

during the first few weeks of treatment. Unprotected exposure to

sunlight, including sunlamps, extreme wind or cold, or use of

irritating skin care products may aggravate the skin.

TELEVISION SCRIPT

JOB # GAD 568

CLIENT	Galderma
PRODUCT	Differin Gel
TITLE	"My Sister's Wedding"
CODE	DIF-11-60
LENGTH	:60
DATE	AS PRODUCED 9/13/01 @ []

BY []

Page 3

VIDEO**AUDIO**

14. Cut to new brochure and Differin Gel.

SUPER:

Call for free brochure
1-800-000-0000

15. Cut to video footage of wedding festivities.

16. Camera shows Meg rolling her eyes.

17. Show Meg and Sue mugging for video camera at wedding.

Differin Gel is available by prescription only, so see your dermatologist. Or call now for a free brochure and a list of dermatologists in your area.

(SFX: wedding ambient, music)

MEG VO: The wedding was great.

MEG OC: But my skin ...

MEG VO: I was radiant!

TELEVISION SCRIPT

JOB # GAD 568

CLIENT	Galderma
PRODUCT	Differin Gel
TITLE	"My Sister's Wedding"
CODE	DIF-10-90R
LENGTH	:90
DATE	AS PRODUCED 9/13/01 @ []
	BY []

Page 1

VIDEO**AUDIO**

1. (Entire spot shot documentary feel, cut back and forth between Meg and Sue talking to camera and real life scenes which they narrate)
(Meg and Sue are both mid-twenties, attractive women)

Open on wedding invitations, coffee cup, pen/paper. Camera pans up to show back of sister's head, mother's head. Camera shows face of Meg. They're planning a wedding. Meg has problem skin.

2. Cut to swish pan across table.
3. Cut to CU of Meg in kitchen setting.
4. Meg in limbo.
Script SUPER: Meg
5. Cut to Meg's bathroom drawer. Full screen. It's full of half-used tubes and pill cases, etc. (Avoid logos)
6. Pan up to her trying to cover a blemish with makeup. Not too effective.

(SFX: ambient sound, music, sound design as appropriate)

MEG VO: My problem? It's not my older sister's wedding ...

to her, ah, fiancé of "four and a half" years ...

MEG VO:

My problem is my skin. My acne.

MEG OC: It's been bad too long. I don't want this for the wedding.

MEG VO:

My bathroom drawer ... full of creams and stuff ...

I've tried everything.

And makeup, doesn't fool anyone.

TELEVISION SCRIPT

JOB # GAD 568

CLIENT Galderma
PRODUCT Differin Gel
TITLE "My Sister's Wedding"
CODE DIF-10-90R
LENGTH :90
DATE AS PRODUCED 9/13/01 @ []
BY []

VIDEO

AUDIO

7. Cut to Meg, limbo.
Script: SUPER: 3 months before the wedding

MEG OC: So today, I'm starting something my cousin told me about:

8. Cut to product on bathroom sink.
Half used.

Differin Gel.

9. Cut to Sue on-camera
Script SUPER: Sue
SUPER: Available by prescription only

SUE OC: I told Meg about Differin Gel. I mean I had worse skin than her.

10. Cut to Sue in limbo.

SUE OC: And look at me now. So I

11. Cut to Sue and Meg having coffee.
SUPER: See our ad in _____
magazine.
(hold for 2 seconds)

(SFX: ambient sound)

SUE VO (narrating): gave her my dermatologist. She got a prescription – just like mine.

12. Move in on Meg's hopeful face.

MEG OC (at lunch): We'll see ... I got a couple of months.

13. Cut to tabletop of Differin and brochure.

.....

SUPER: #1 prescribed topical drug by dermatologists

SUE VO (narrating): My doctor said Differin Gel may change how your skin cells work.

14. Cut to Meg, at home, in bathroom at night. Applying Gel.

You use a little dab at night. It's oil-free with no alcohol.

TELEVISION SCRIPTJOB # GAD 568

CLIENT Galderma
 PRODUCT Differin Gel
 TITLE "My Sister's Wedding"
 CODE DIF-10-90R
 LENGTH :90
 DATE AS PRODUCED 9/13/01 @ []

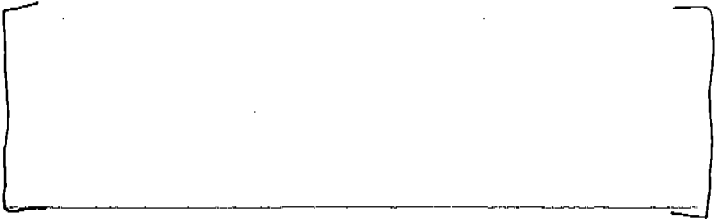
BY []

Page 3

VIDEO**AUDIO**

- | | |
|---|--|
| <p>15. Cut to real before/after and product tube. SUPER:.
 1-800-000-0000
 SUPER: before/after
 Individual results may vary.</p> | <p>All I can say is ... having clearer skin,</p> |
| <p>16. Another real before/after.
 SUPER:
 Individual results may vary.</p> | <p>It just changes everything.</p> |
| <p>17. Cut to Meg, clearer skin, in kitchen.</p> | <p><u>MEG OC</u> (narrating):</p> |
| <p>18. Sue and Meg in bridal salon.
 Camera catches quick audio interchange between them.
 SUPER: 1 month before the wedding</p> | <p>I see improvement.</p> <p><u>SUE OC</u>: (to Meg, commenting on her skin) You look good ...</p> <p><u>MEG OC</u>: (To Sue) I owe you one.</p> <p><u>SUE OC</u>: (to Meg, laughing) Yeah, you do.</p> |
| <p>19. In letterbox, montage of Meg and Sue and wedding shots.
 SUPER: 1-800-000-0000
 www.DifferinGel.com
 SUPER:
 Now available as a cream

 Change SUPER: Use of sunscreen is recommended.</p> | <p>Itching, dryness, redness, burning or peeling may occur especially during the first few weeks of treatment. Unprotected exposure to sunlight, including sunlamps, extreme wind or cold, or use of irritating skin care products may aggravate the skin.</p> |
| <p>20. Cut to brochure and Differin Gel.
 SUPER: #1 prescribed topical drug by dermatologists
 SUPER:
 Call for free brochure
 1-800-000-0000</p> | <p>Differin Gel is available by prescription only, so see your dermatologist. Or call now for a free brochure and a list of dermatologists in your area.</p> |



TELEVISION SCRIPT

JOB # GAD 568

CLIENT Galderma
PRODUCT Differin Gel
TITLE "My Sister's Wedding"
CODE DIF-10-90R
LENGTH :90
DATE AS PRODUCED 9/13/01 @ []
BY []

VIDEO

AUDIO

21. Meg on-camera at home.

(SFX: wedding ambient, music)

MEG VO: The wedding was great.

22. Camera shows Meg rolling her eyes.

MEG OC: Our dresses ... eh... ..

23. Show Meg and Sue at reception.

MEG VO:

But my skin.

24. Meg and Sue at reception.

MEG VO: I was radiant!